



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 493

[CMS-3326-CN]

RIN 0938-AT47

### **Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories; Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical and typographical errors in the final rule that appeared in the December 28, 2023, **Federal Register** entitled, “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories” (referred to hereafter as the “December 2023 final rule”).

**DATES:** This correction is effective January 27, 2024.

**FOR FURTHER INFORMATION CONTACT:** Penny Keller, CMS, (410) 786-2035; or Heather Stang, CDC, (404) 498–2769.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In FR Doc. 2023-28170 of December 28, 2023, the December 2023 final rule (88 FR 89976), there were technical and typographical errors that are identified and corrected in this correcting document. These corrections are effective as if they had been included in the December 2023 final rule.

##### **II. Summary of Errors in the Regulation Text**

On page 90040, in the revision for § 493.1423(b)(7)(i), we inadvertently omitted two redesignated paragraph references for individuals who meet the regulatory qualifications to perform blood gas analysis. We are correcting the revision for § 493.1423(b)(7)(i) to include references to § 493.1423(b)(5) and (6).

On page 90043, in amendatory instruction 30, we inadvertently omitted the specific paragraph references for the changes to paragraph (e), which were set out in the amendment text. We are correcting the instruction to specify paragraphs (e)(1) through (4).

On page 90044, in the revisions for § 493.1483(b)(3), we inadvertently omitted the December 28, 2024 effective date.

On page 90044, in amendatory instruction 37, we inadvertently included an incorrect effective date. The December 2023 final rule contained two separate effective dates, January 27, 2024, and December 28, 2024 and we erroneously included the December 28, 2024, effective date rather than the January 27, 2024, effective date.

### **III. Waiver of Proposed Rulemaking and Delay in Effective Date**

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**.

Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest. In addition, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe this correcting document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document merely corrects technical and typographical errors in the December 2023 final rule but does not make substantive

changes to the policies that were adopted in the December 2023 final rule. Instead, this correcting document is intended to ensure that the information in the December 2023 final rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the December 2023 final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest to ensure that the December 2023 final rule accurately reflects the policies finalized in that final rule. Furthermore, such procedures would be unnecessary, as we are not altering our policies, but rather, we are simply correctly implementing the policies we finalized. This final rule correction is intended to ensure that the December 2023 final rule accurately reflects those policies. Therefore, we believe we have good cause to waive the notice and comment and delayed effective date requirements.

#### **IV. Correction of Errors in the Regulation Text**

In FR Doc. 2023-28170 of Thursday, December 28, 2023 (88 FR 89976), we are making the following corrections:

##### **§ 493.1423 [Corrected]**

1. On page 90040, in the third column, in § 493.1423(b)(7)(i), “(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or” is corrected to read “(i) Be qualified under paragraph (b)(1), (2), (3), (4), (5), or (6) of this section; or”.

##### **§ 493.1461 [Corrected]**

2. On page 90043, in the third column, amendment 30, the instruction “Effective December 28, 2024, amend § 493.1461 by revising paragraphs (c), (d)(3)(i), and (e) to read as follows:” is corrected to read “Effective December 28, 2024, amend § 493.1461 by revising paragraphs (c), (d)(3)(i), and (e)(1) through (4) to read as follows:”.

##### **§ 493.1483 [Corrected]**

3. On page 90044, in the second column, in § 493.1483(b)(3), “(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since December 28, 2024” is corrected to read “(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024”.

**§ 493.1804 [Corrected]**

4. On page 90044, in the third column, amendment 37, the instruction “Effective December 28, 2024, amend § 493.1804 by revising paragraph (c)(1) to read as follows:” is corrected to read “Effective January 27, 2024, amend § 493.1804 by revising paragraph (c)(1) to read as follows:”.

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**Elizabeth J. Gramling,**

Executive Secretary to the Department,

Department of Health and Human Services.

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